U.S. Serial No. 10/646,108 Filed: August 22, 2003

Group Art Unit: 3736 Examiner: Rogers, Kristin D

Docket No.: 022719-0045

# REMARKS

The pending final Office Action addresses and rejects claims 1-4 and 6-33.

#### Amendments to the Claims

Claim 6 is amended to recite that the "flexible membrane" is formed in the sidewall of the catheter. No new matter is added.

#### Claim Objections

Claim 6 is objected to for failing to identify the subject matter formed in the sidewall of the catheter. The claim is amended as noted above to correct this typographical error.

### Rejections Pursuant to 35 U.S.C. §103

(1) Claims 1-4, 6, 9-10, 21-23, and 28-30

Claims 1-4, 6, 9-10, 21-23, and 28-30 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 4,928,693 of Goodin in view of U.S. Patent No. 5,573,007 of Bobo Sr. The Examiner argues that Goodin discloses the claimed invention, but admits that Goodin fails to teach the use of a flexible membrane. Thus, the Examiner relies on Bobo to teach a pressure monitoring catheter having a flexible membrane disposed across an opening formed in a sidewall. Further, the Examiner admits that Goodin does not expressly disclose a pressure sensor, but that this features is inherently and is also taught by Bobo. Applicants disagree.

First, modifying Goodin to include a flexible membrane disposed across an opening formed in the catheter would render the device inoperative for its intended use. Goodin appears to indicate that the lumen is not sealed, and thus does not include any type of flexible membrane. At Col. 2, lines 50-57, Goodin states that:

Alternatively, the catheter may include two blood pressure measuring lumens, one exiting the distal end of the catheter and the other ending proximally a predetermined distance from the distal end and with a port

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extending through the wall of the catheter in fluid communication with the shorter lumen. Readings can be simultaneously taken through both lumens without moving the catheter.

As stated in the response filed on November 28, 2006, while this passage is directed to an alternative embodiment, in this embodiment neither lumen is sealed. Goodin makes it clear that the first lumen exits the distal end, and the second shorter lumen has a port extending through the wall of the catheter. Readings are still taken through the open lumens. Based on this language, a person having ordinary skill in the art could conclude that lumen (20) of the first embodiment is likewise open and is not sealed. While Col. 4, lines 11-29 of Goodin explains that the lumen can be filled with an incompressible fluid, it is possible for the distal end (14) of the lumen to remain open to receive blood flow therethrough. The fluid could be added during the procedure to eliminate the need for the blood to flow through the entire length of the catheter, and/or to prevent blood from flowing into the external blood pressure measuring equipment. Thus, the addition of a membrane such as the one taught by Bobo would change the operation of the device of Goodin since the teachings of Goodin appear to suggest that the lumen is open and does not include any type of flexible membrane.

Second, the Examiner has failed to provide the required motivation for making such a modification. The strongest rational for combining references is a recognition that some advantage of expected beneficial result would be produced by the combination. (See MPEP 2144). There is no advantage to adding the flexible membrane of Bobo to the Goodin device because, as explained above, the Goodin disclosure suggests that the lumens are not sealed. Thus, the addition of the membrane would provide no advantage as it would inhibit the way in which the device measures pressure.

Third, it would not be possible to add the pressure sensor to the Goodin device, at least not without significantly modifying the device. Goodin does not teach a catheter having a pressure sensor. To the contrary, it appears that the pressure sensor is part of external measuring equipment, and does not form part of the catheter. See, e.g., Col. 4, lines 22-23, which state that the blood pressure is "transmitted through the fluid to the proximal end 16 of the catheter, and from there to the blood pressure measuring equipment . . . ." (Col. 4, lines 22-23). Thus, in order to add a pressure sensor, the device of Goodin would be have to modified to accommodate this additional component.

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Accordingly, no person having ordinary skill in the art would modify the catheter of Goodin to include a flexible membrane disposed across an opening, as taught by Bobo, and therefore claims 1, 22, and 29, and claims 4, 6, 9-10, 21, 23, 28, and 30 which depend therefrom, distinguish over Goodin and Bobo and represents allowable subject matter.

# (2) Claims 7, 8, 11-20, 25-27, 31-33

Claims 7, 8, 11-20, 25-27, and 31-33 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over Goodin in view of various references set forth in the Office Action. The Examiner relies on these references to teach various features recited in the dependent claims and not taught by Goodin. As indicated above, Goodin does not teach a catheter having a sealed lumen extending between a flexible membrane disposed across an opening formed in the catheter and a sensor. The various secondary references cited by the Examiner do not remedy these deficiencies of Goodin. Accordingly, claims 7, 8, 11-20, 25-27, and 31-33 distinguish over Goodin and the various secondary references and represent allowable subject matter.

#### (3) Claims 24 and 30

Claims 24 and 30 are rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over Goodin in view of U.S. Patent No. 5,573,007 of Bobo, Sr. The Examiner relies on Bobo to teach various features not taught by Goodin. Claims 24 and 30 depend from claim 22 and 29 and are therefore allowable at least because claims 22 and 29 are allowable. Further, the Examiner has failed to establish a prima facie case of obviousness, as noted above, with regard to Goodin and Bobo. Accordingly, claims 24 and 30 distinguish over Goodin and Bobo and represents allowable subject matter.

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# Conclusion

Applicants submit that all pending claims are now in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

Respectfully submitted,

Date: <u>March 23, 2007</u>

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